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Index: Medical Benefit

TO: All County California Children Services (CCS), State Children Medical Services (CMS) Regional Offices, Genetically Handicapped Persons Program (GHPP), and State CMS Staff

SUBJECT: CONTINUOUS SUBCUTANEOUS INSULIN INFUSION (CSII) OR "INSULIN PUMP" THERAPY FOR TYPE I DIABETES MELLITUS

I. BACKGROUND

CSII (or insulin pump therapy) was instituted in the late 1970s as an additional treatment modality for insulin-dependent diabetes mellitus. The goal of CSII is to achieve near-normal glycemic control over 24 hours per day with normalization of the glycosylated hemoglobin level. The use of CSII has been shown to improve growth in children, decrease the incidence of hypoglycemia, lower elevated lipids, and arrest the progression of retinopathy.

The insulin pump is an open-looped system that has two modes of insulin delivery. First, there is a continuous basal infusion of insulin that can be pre-programmed to the blood glucose level of the individual patient and can be automatically adjusted to accommodate fluctuations in blood sugar, such as the "dawn phenomenon." The second mode of delivery is a bolus of insulin that is used for meals and snacks and for correction of elevated blood glucose levels.

CSII has been proven to stabilize the glycemic control in the patient with Type 1 diabetes mellitus. The advantages of CSII are that it affords more flexibility of life-style for the patient with less variability of insulin absorption, more precise insulin administration matched with food intake and activity levels, and overall close attention to diabetes management. A potential disadvantage of the insulin pump is the possibility of interruption of insulin delivery occurring as a result of mechanical failure of the pump or dislodgment or obstruction of the infusion catheter. Because of the use of insulin lispro (which has a short duration of action) with the pump, pump therapy cannot be interrupted for greater than three hours without significant ketoacidosis occurring. CSII at this time is generally not recommended for patients under ten years of age, but may be recommended

for younger children with exceptional needs when combined with a high level of parental knowledge and intense supervision of diabetes management.

II POLICY GUIDELINES

A. Effective the date of this letter, CSII is a benefit of the CCS program for patients eligible for CCS with diabetes when requested by a CCS-approved Metabolic/Endocrine Special Care Center (SCC) physician, and there is documentation provided at the time of the request of:

Frequent erratic swings in blood glucose levels requiring multiple visits to physicians, emergency rooms, or hospitals that can be documented by any of the following:

- significant ketosis, in spite of strict dietary control and daily multiple insulin injections;
- insulin reactions and/or ketoacidosis, including unawareness of hypoglycemia;
- blood glucose levels > 140 mg/dL preprandially and /or
  >200 mg/dL fasting ("dawn phenomenon");

  glycosylated hemoglobin (Hb A1c) > 8.0 percent;
- pregnancy with complications resulting from diabetes mellitus;

  chronic renal failure and/or ongoing dialysis;
- early complications, such as diabetic retinopathy, peripheral neuropathy, renal problems, or other complications related directly to diabetes mellitus;
- poor linear growth that is attributed to poor glycemic control;

  other extenuating factors will be considered with medical justification provided by the Metabolic/Endocrine SCC physician; and

Patient demonstrating the maturity and ability to self-monitor glucose levels at least four times per day; and

3. Patient demonstrating compliance with recommended diet; and

4. Patient demonstrating that he/she has sufficient knowledge, skills, and attitudes to enable him/her to manage the essentials of CSII **independently**, and/or patient has very strong **parental support and supervision** until patient is able to manage the pump independently; and

5. Patient's and family's high level of motivation to achieve and maintain glycemic control and to understand the benefits of this control.

B. Continuing use of the insulin pump must be supervised by the SCC physician at the CCS-approved Endocrine/Metabolic SCC. Annual SCC evaluations, including additional visits with core team members as deemed necessary by the SCC physician, must be continued.

C. The patient will remain medically eligible for CCS for the **duration of insulin pump use.**

III. IMPLEMENTATION GUIDELINES

A. The CCS program medical consultant or designee shall

1 review the request for the CSII to ensure that the request is from the CCS-authorized Metabolic/Endocrine SCC physician.

2 ensure that the request is accompanied with the necessary documentation to determine medical necessity that includes a current SCC evaluation, with appropriate documentation by the center physician, the social worker, the nutritionist, and the nurse specialist.

3 ensure that the Metabolic/Endocrine SSC physician communicates information about the CSII with the local CCS-paneled community pediatrician. If the child does not have a local CCS-paneled pediatrician, the CCS program medical director or designee or the SCC physician shall aid the family in selecting a local doctor.

B. Authorizations

1 Initial authorization for the insulin pump and pump supplies will be for a one year-period or up to the expiration of program eligibility (whichever comes first).

- the pump can be authorized for either rental [HCPCS code E0784 (rental, per month)] or purchase [HCPCS code E0784 with modifier Y-7]; and

- supplies, i.e., replacement infusion sets/syringes [HCPCS code A4230 - A4232)].

2 There shall be a separate authorization to the SCC to cover the **outpatient** evaluation and training services for the **initiation** of the pump (as an **ambulatory** service only) provided by the SCC core team. As a result of this authorization, the SCC can bill up to eight **total** visits during the first two months of pump therapy by non-physician core team members who provide support to the patient/family, such as a nutritionist, nurse specialist, or social worker.

3. Initial authorization of the pump and pump supplies should be accompanied by an authorization for a monthly visit to a non-physician core team member for oversight and monitoring of the use of the pump.

4. Re-authorizations of the pump and pump supplies will be dependent upon documentation by the SCC physician of need for continuation of the pump.

5. Re-authorizations of the pump and pump supplies will be for a one- year period or up to the expiration of program eligibility (whichever comes first).

6. Re-authorization of the pump and pump supplies should be accompanied by an authorization for a monthly visit to a non-physician core team member responsible for oversight and monitoring of the use of the pump.

7. As the insulin pump is already a Medi-Cal benefit, the CCS program can authorize the pump and supplies for Medi-Cal-eligible children who meet the criteria in II. A. above.

8. Any **denial** of the CSII shall be made by the CCS program medical director.

If you have any questions, please contact Karlette Winters, M.D., at (916) 657-0179.

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